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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,342	11/05/2001	Gary Blackburn	A-68718-4/RFT/RMS/RMK	5809

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EXAMINER

REDDING, DAVID A

ART UNIT PAPER NUMBER

1744

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/993,342		BLACKBURN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	David A Redding		1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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## **DETAILED ACTION**

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

See Signature of inventor Olsen.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. In the amendment filed 7/02 applicant asserts support for claim 13 in figures 1 and 2 and specification at page 2, lines 16-23. However, the structural elements of claim 13 are not identified at those locations. Therefore, the structural elements defined in claim 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: page 3, lines 11-13 applicant specifies "reaction chamber 105" in figure 2; "inlets and outlets (100, 101) in figure 1G; "microchannel 110, silicon gasket 104B in 1G.

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However, the figures are not commensurate with these disclosures. In Figure 3C the electrode array is misnumbered (112); it should be numbered (103).

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Double Patenting***

Claim 32 of this application conflict with claim 14 of Application No. 10/193,712; claim 14 of Application No. 10/412,660. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13,22,23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 09/760,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because the 09/760,384 claims are anticipated by instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13, 22,23, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2,3,5,6-34 of copending Application No. 09/904,175. Although the conflicting claims are not identical, they are not patentably distinct from each other because the 09/904,175 claims are anticipated by the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13,25-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,7-13 of copending Application No. 10/193,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the 10/193,712 application are anticipated by the instant claims.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13,14,20,31,32, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-46 of copending Application No. 10/199,948. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the 10/199,948 are anticipated by the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13,25-27, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,7-13 of copending Application No. 10/412,660. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the 10/412,660 application are anticipated by the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15,16,18,28, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.

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See MPEP § 2172.01. The omitted structural cooperative relationships are: the cap to the cartridge; the thermal heater to the cartridge; the pump to the cartridge.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13-25, 28-31, are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,168,948 B1 (Anderson et al.).

The Anderson patent discloses an integrated nucleic acid diagnostic device which includes a microfluidic cartridge (figures 2b, 3) comprising a reaction chamber for performing DNA amplification reaction, a detection chamber connected to the reaction chamber for identifying the DNA. The detection chamber is disclosed as having an array of probed coupled to an electrode array (figure 49 and 50).

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See column 12 thru col. 15, line 12; col.17 thru col.38, line 48. The use of heaters is disclosed in col.25, lines 28-65. Using air bubbles to mix the reactants is disclosed in col.51, lines 25-37; the embodiments of claim 20 are disclosed in col.15, lines 1-12; the embodiments of claim 21 are disclosed in col.29, lines 60-67; the embodiments of claims 24,25 are disclosed in col.28, lines 4-9; the embodiments of claims 28,29,30, are disclosed in col. 28, line 60 thru col. 29, line 15; the embodiment of claim 31 are disclosed in col. 32, lines 41-60.

Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,14,122 (Besemer et al.).

Figure 4 illustrates the embodiment claimed. See the description of figure 4.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.



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Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,168,948 B1 in view of USP 6,632,399 (Kellogg et al.).

The '948 patent is silent as to the use of "burst" valves. The Kellogg et al. patent discloses a microfluidic assay device which discloses the use of polymeric "burst" valves to control the flow of fluid within the channels (col.45, lines 62-67). It would have been obvious to one skilled in the art to replace one of the duck-bill valves or sliding valves in the '948 patent with a polymeric "burst" valve in view of the known use to control the flow of fluids in the microfluidic device disclosed in Kellogg et al.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The remaining US patents cited are considered to be closely related to the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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